NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

NOVARTIS AG and NOVARTIS PHARMACEUTICALS CORPORATION, Plaintiffs, v. MYLAN PHARMACEUTICALS, INC. and MYLAN INC., Defendants.	Civil Action No.: 09-cv-3604 (PGS) **MEMORANDUM & ORDER**

Plaintiffs Novartis AG and Novartis Pharmaceuticals Corporation (collectively Novartis), have brought this Hatch-Waxman patent suit against Defendants Mylan Pharmaceuticals, Inc. and Mylan Inc. (collectively Mylan),[1] claiming that Mylan has infringed on Novartis's patents by filing an Abbreviated New Drug Application (ANDA) with the U.S. Food and Drug Administration, which seeks approval to market generic versions of 180 mg and 360 mg delayed-release mycophenolate salt products.[2] Novartis claims that the ANDA infringes three of its patents-in-suit – U.S. Patent Nos.

[1] A companion case, *Novartis AG v. Apotex Inc.*, No. 09-5614, was consolidated with the instant action for pretrial purposes. However, that action was stayed on July 5, 2011, for a period of forty-five days to permit government approval of a settlement agreement between Novartis and Apotex. Consequently, this claim construction opinion pertains only to those terms in dispute between Novartis and Mylan.

[2] Mycophenolate monosodium salt is the active ingredient in Novartis's drug Myfortic®, which is FDA approved for the prophylaxis of organ rejection in patients receiving allogeneic renal (kidney) transplants, administered in combination with other drugs.

6,025,391 ("the '391Patent"), 6,172,107 ("the '107 Patent"), and 6,306,900 ("the '900 Patent").[3] Presently before the Court is the parties' request for claim construction.

Novartis filed suit against Mylan on July 17, 2009. On May 6, 2010, the parties filed a Joint Claim Construction and Prehearing Statement. The parties filed their Opening and Responsive Claim Construction Briefs on December 14, 2010. The Court held a *Markman* hearing on the disputed terms on April 28, 2011. This Opinion addresses the proper construction of six disputed terms.[4]

I. STANDARDS FOR CLAIM CONSTRUCTION

There is a two-step process for analyzing patent infringement: "first, the court determines the meaning of the disputed claim terms, then the accused device is compared to the claims as construed to determine infringement." *Acumed LLC v. Stryker Corp.*, 483 F.3d 800, 804 (Fed. Cir. 2007) (citation omitted). Determining the meaning of dispute claim terms, which is the first step, is referred to as claim construction. The construction of claims may be decided as a matter of law. *Markman v. Westview Instruments*, 517 U.S. 370, 372 (1996). "[T]he construction of a patent, including terms of art within its claim, is exclusively within the province of the court." *Id.*

When construing claims, the Court must focus on the language of the claim. As explained by the Federal Circuit:

> It is a bedrock principle of patent law that the claims of a patent define the invention to which the patentee is entitled the right to exclude. Attending this principle, a claim construction analysis

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[3] The patents-in-suit relate to coated compositions, which contain mycophenolate salts.

[4] At the time of the *Markman* hearing, the parties requested claim construction for twelve disputed terms. However, on July 15, 2011, the parties apprised the Court that it need only construe six terms.

> must begin and remain centered on the claim language itself, for that is the language the patentee has chosen to particularly point out and distinctly claim the subject matter which the patentee regards as his invention.

Innova/Pure Water, Inc. v. Safari Water Filtration Sys., 381 F.3d 1111, 1115-16 (Fed. Cir. 2004) (internal citations, quotation marks, and editing marks omitted). When looking at the words of a claim, the words "are generally given their ordinary and customary meaning," which has been defined as "the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention, i.e., as of the effective filing date of the patent application." *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312-13 (Fed. Cir. 2005).

The Federal Circuit has counseled:

> It is the person of ordinary skill in the field of the invention through whose eyes the claims are construed. Such person is deemed to read the words used in the patent documents with an understanding of their meaning in the field, and to have knowledge of any special meaning usage in the field. The inventor's words that are used to describe the invention – the inventor's lexicography – must be understood and interpreted by the court as they would be understood and interpreted by a person in that field of technology. Thus the court starts the decision making process by reviewing the same resources as would that person, viz., the patent specification and prosecution history.

Id. at 1313 (quoting *Multiform Desiccants, Inc. v. Medzam, Ltd.*, 133 F.3d 1473, 1477 (Fed. Cir. 1998)). Those resources, called intrinsic evidence, include the claim language, the specification, and the prosecution history. *See id.* at 1314.

However, when intrinsic evidence alone does not resolve the ambiguities in a disputed claim term, extrinsic evidence – evidence that is outside the patent and prosecution history – may also be used to construe a claim. *See id.* at 1317; *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582-83 (Fed. Cir. 1996). "[E]xtrinsic evidence concerning relevant scientific principles, the meaning of

technical terms, and the state of the art" may be consulted; for example, expert testimony, dictionaries, and treatises. *Id.* at 1314. However, when a Court relies on extrinsic evidence to construe a claim, the Court should be guided by the principle that extrinsic evidence may never conflict intrinsic evidence, because Courts "have viewed extrinsic evidence in general as less reliable than the patent and its prosecution history in determining how to read claim terms." *Id.* at 1319. Thus, a Court should take care to "attach the appropriate weight to be assigned to those sources." *Id.* at 1322-24.

II. THE DISPUTED CLAIM TERMS[5]

A. Term 1 – "pharmaceutically acceptable mycophenolate salt"

Term 1 appears in claims 2, 3, and 4 of the '391 Patent and claim 10 of the '900 Patent. Novartis's proposed construction for this term is as follows: "a salt suitable for pharmaceutical use formed by an anion of mycophenolic acid and a cation, including the monosodium salt." Conversely, Mylan argues for the following construction: "any cationic salt of mycophenolic acid."

Novartis maintains that Mylan's construction should be rejected because it impermissibly reads the "pharmaceutically acceptable" limitation out of the claim. However, Mylan posits that Novartis's construction is improper because it introduces extraneous or other limiting elements into the claim, primarily "pharmaceutically acceptable." Thus, the main dispute between the parties is whether the language "pharmaceutically acceptable" should be included in the construction of this term.

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[5] The Court has accepted the agreed upon construction of four terms: (1) "pharmaceutical composition" means "a drug composition," (2) "upper part of the intestinal tract" means "the duodenum, jejeunum and/or ileum," (3) "suitable as an immunosuppressant medicament" means "a drug that is suitable to suppress an immune response," and (4) "crystalline form" means "crystalline form (as distinguished from amorphous form)."

In the intrinsic evidence there is deference to the term pharmaceutically acceptable. For example, in one reference, the specification states:

> In a further aspect the invention provides a pharmaceutical composition comprising a coated pharmaceutically acceptable mycophenolate salt.
>
> Such salts are cationic salts, e.g. of alkali metals, especially the sodium salts. Sodium mycophenolate salts are known, e.g., in South African Patent 68/4959. We prefer to use the monosodium salt.

('391 Patent, col. 1, ll. 55-61, '107 Patent, col. 1, ll. 59-65, '900 Patent, col. 1, ll. 59-65). In addition to the description of cationic salts, the specification provides that "other pharmaceutically acceptable ingredients may be present . . . e.g. fillers, e.g. lactose, glidants." ('391 Patent, col. 2, ll. 17-21). Further, the Court also finds the following evidence from one U.S. Patent and two Great Britain Patents referring to pharmaceutically acceptable:

> U.S. Patent No. 4,727,069, col. 6, ll. 33-39:
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> A "pharmaceutically acceptable salt" may be any salt derived from an inorganic or organic acid or base. The term "pharmaceutically acceptable anion" refers to the anion of such acid addition salts. "Pharmaceutically acceptable cation" refers to the cation of such base addition salts. The salt, the anion, and/or the cation are chosen not to be biologically or otherwise undesirable.
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> Great Britain Patent No. 1,157,099, p. 2, ll. 93-105:
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> As a suitable salt of mycophenolic acid which may be manufactured according to this invention there may be mentioned any salt containing a non-toxic pharmaceutically acceptable cation, for example an alkali metal salt, for example a sodium salt, or an alkaline earth metal salt, or an ammonium salt, or a salt with an organic base affording a non-toxic, pharmaceutically-acceptable cation. It is to be understood that the salts include salts which involve only the carboxy radical of mycophenolic acid, for example the monosodium salt . . .
>
> .

Great Britain Patent No. 1,157,100, p.1, ll. 38-48:

> As a suitable salt of mycophenolic acid there may be mentioned a salt having a non-toxic pharmaceutically-acceptable cation, for example an alkali metal salt, for example a sodium salt, or an alkaline earth metal salt, an ammonium salt, or a salt with an organic base which affords a non-toxic, pharmaceutically-acceptable cation. It is to be understood that the salts include salts which involve only the carboxy radical of mycophenolic acid, for example the monosodium salt . . . .

The language from the U.S. Patent explains that the cation to be chosen may not "be biologically or otherwise undesirable" and the Great Britain Patent specifications call for "any salt containing a non-toxic pharmaceutically acceptable cation." Such language is illuminating as it evidences that there are toxic cations and non-toxic cations. Logically, a toxic cation would not be pharmaceutically acceptable. A person of ordinary skill in the art (POSA) viewing the disputed language in the context of the claims would understand such and would avoid any construction including toxic cations. In light of such intrinsic evidence, as well as the principle that "[a] claim construction that gives meaning to all the terms of the claim is preferred over one that does not do so," *Merck & Co., Inc. v. Teva Pharms. USA, Inc.*, 395 F.3d 1364, 1372 (Fed. Cir. 2005) (citation omitted), the Court concludes that the proper construction of this term is "any pharmaceutically acceptable cationic salt (preferably monosodium) of mycophenolic acid."

B. Term 2 – "enteric coated" and "enteric coating"

The term "enteric coated" appears in claims 2, 3, and 4 of the '391 Patent, whereas the term "enteric coating" appears in claims 2, 3, and 6 of the '107 Patent and claims 2 and 11 of the '900 Patent. Novartis advances the following construction of this term: "any pharmaceutically acceptable coating preventing the release of the active agent in the stomach and sufficiently disintegrating in

the intestine tract (by contact with approximately neutral or alkaline intestine juices) to allow the resorption of the active agent through the walls of the intestinal tract." Mylan advances the following construction: "any pharmaceutically acceptable coating preventing the release of the active agent in the stomach."

As previously noted, the words of a claim "are generally given their ordinary and customary meaning," which has been defined as "the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention, i.e., as of the effective filing date of the patent application." *Phillips*, 415 F.3d at 1312-13. "'Importantly, the person of ordinary skill in the art is deemed to read the claim term not only in the context of the particular claim in which the disputed term appears, but in the context of the entire patent, including the specification.'" *Callicrate v. Wadsworth Mfg.*, 427 F.3d 1361, 1367 (Fed. Cir. 2005) (quoting *Phillips*, 415 F.3d at 1313). The Court of Appeals for the Federal Circuit has counseled that the "specification is always highly relevant to the claim construction analysis. Usually it is dispositive; it is the single best guide to the meaning of a disputed term." *Wellman, Inc. v. Eastman Chem. Co.*, 2011 U.S. App. LEXIS 8903, *29 (Fed. Cir. Apr. 29, 2011) (quoting *Phillips*, 415 F.3d at 1315).

"In some cases, the ordinary meaning of claim language as understood by a person of skill in the art may be readily apparent even to lay judges, and claim construction in such cases involves little more than the application of the widely accepted meaning of commonly understood words." *Phillips*, 415 F.3d at 1314. However, because patent law permits a patent applicant to be a lexicographer, the Court must always look to see if the applicant has modified the meaning of a word or assigned meaning to a word that is inconsistent with the ordinary or accustomed meaning of the word. *See John D. Watts v. XL Sys., Inc.*, 232 F.3d 877, 883 (Fed. Cir. 2000) (explaining "even if

[the claims] were clear on their face, we must consult the specification to determine if the patentee redefined any of those terms" (citing *Vitronics*, 90 F.3d at 1582)). "When a patentee explicitly defines a claim term in the patent specification, the patentee's definition controls." *Martek Biosciences Corp. v. Nutrinova, Inc.*, 579 F.3d 1363, 1380 (Fed. Cir. 2009) (citing *Phillips*, 415 F.3d at 1321 ("[T]he specification acts as a dictionary when it expressly defines terms used in the claims."); *id.* at 1316 ("[O]ur cases recognize that the specification may reveal a special definition given to a claim term by the patentee that differs from the meaning it would otherwise possess. In such cases, the inventor's lexicography governs.")).

In this case, the term "enteric coating," is expressly defined in each of the patent specifications:

> The term "enteric coating" comprises any pharmaceutically acceptable coating preventing the release of the active agent in the stomach and sufficiently disintegrating in the intestine tract (by contact with approximately neutral or alkaline intestine juices) to allow the resorption of the active agent through the walls of the intestinal tract.

('391 Patent, col. 2, ll. 22-27; '107 Patent, col. 2, ll. 25-30; '900 Patent, col. 2, ll. 25-30). Accordingly, that definition – Novartis's proposed construction – controls.

Mylan argues, however, that the construction of "enteric coating" should be limited for several reasons. First, Novartis's construction is inconsistent because resorption is a common medical term referring to the re-absorption of a substance and an oral pharmaceutical composition. An oral pharmaceutical composition cannot be reabsorbed or subject to resorption because it has not yet been absorbed in the first place. In response, Novartis asserts that the meaning of "resorption," as used in the specification means absorption. The Court agrees with Novartis.

Although the Court finds that the use of the word "resorption" is peculiar and that the specification does not give a straightforward definition of the word, the Court nevertheless finds that a POSA reviewing the entire specification would understand that resorption means absorption in this context because an active agent – in this case the pharmaceutically acceptable mycophenolate salt – may not be absorbed until released from the enteric coating. Here the enteric coating prevents the release of the active agent in the stomach and disintegrates in the intestinal tract allowing absorption to occur. Thus, the active agent cannot be reabsorbed in the intestinal tract because the active agent was not previously exposed in the stomach. Therefore, when read in view of the entire specification, and in the context of the specification in which it appears, the word resorption means absorption. Accordingly, the Court is not persuaded that Novartis's construction is flawed by the word "resorption."

Second, Mylan contends that the specification contains a "second express definition" of "enteric coating," which is inconsistent with the first definition. Mylan points to the following language, which is located in the paragraph after the first definition in all three Patent specifications:

> More specifically, the term "enteric coating" as used herein refers to a coating which remains intact for at least 2 hours, in contact with artificial gastric juices such as HCI or pH1 at 36 to 38 °C and preferably thereafter disintegrates within 30 minutes in artificial intestinal juices such as KH_2PO_4 buffered solution of pH 6.8.

('391 Patent, col. 2, ll. 31-36; '107 Patent, col. 2, ll. 34-39; '900 Patent, col. 2, ll. 34-39). According to Mylan, such language is inconsistent with the first definition because the use of the word "preferably" in the second definition "indicat[es] that where and how the coating disintegrates is only an optional property of an 'enteric coating'." Defendants further posit that inclusion of an optional characteristic in the definition of "enteric coating" would convert such characteristic into a

mandatory characteristic. Novartis argues that the alleged "second express definition" is not a definition, but would be understood by a POSA to be a description of testing procedures. Reviewing the word "preferably" in the context of the specification, it appears to the Court that the term "preferably"refers to the timing of the disintegration, not whether disintegration of the enteric coating will occur at all.

In sum, the construction of Term 2 is "any pharmaceutically acceptable coating preventing the release of the active agent in the stomach and sufficiently disintegrating in the intestine tract (by contact with approximately neutral or alkaline intestine juices) to allow the resorption of the active agent through the walls of the intestinal tract," and the word "resorption" means "absorption."

C. Terms 3, 4 & 5 – "adapted to prevent release of the mycophenolate salt in the stomach and to release the mycophenolic salt in the upper part of the intestinal tract"; "adapted to prevent release of mycophenolate in the stomach"; and "adapted to prevent release"

These terms appear in claim 1 of the '391 Patent and in claims 1 and 11 of the '900 Patent. However, Term 5 – "adapted to prevent release" – is subsumed within Terms 3 and 4. Nevertheless, the words "adapted to prevent release" appear to be the only words in dispute in Term 3 – "adapted to prevent release of the mycophenolate salt in the stomach and to release the mycophenolic salt in the upper part of the intestinal tract." In the Court's view, construction of both Terms 3 and 5 would be duplicative; therefore, the Court need only interpret Terms 3 and 4.

1. Term 3: "adapted to prevent release of the mycophenolate salt in the stomach and to release the mycophenolic salt in the upper part of the intestinal tract"

Novartis posits the construction of Term 3 should be: "adapted with a pharmaceutically acceptable coating to prevent release of the mycophenolate salt in the stomach and to release the mycophenolate salt in the upper part of the intestinal tract." Mylan maintains the construction should

be: "formulating the composition with any pharmaceutically acceptable coating that remains intact in the stomach to prevent release of the mycophenolate salt in the stomach and to release the mycophenolate salt in the duodenum, jejeunum and/or ileum." The Court notes that there is no difference between the parties' proposed construction of "upper part of the intestinal tract" and "in the duodenum, jejeunum and/or ileum." As previously mentioned, the parties have already agreed that the proper construction of "upper part of the intestinal tract" is "the duodenum, jejeunum and/or ileum." Thus, the parties' disagreement over the proper construction of this term focuses on Mylan's insertion of "remains intact."

Mylan argues that the specification and relevant treatises show that compositions "adapted to prevent release" are limited to a coating that remains intact in the stomach. Mylan asserts that the patents-in-suit disclose only a single adaptation to prevent release of the composition – an enteric coating, i.e., "any pharmaceutically acceptable coating preventing the release of the active agent in the stomach." ('391 Patent, col. 2, ll. 22-24). In addition, Mylan observes that the specification states that the enteric coating "remains intact" in the stomach. ('391 Patent, col. 2, ll. 32). Therefore, Mylan posits that "adapting the composition of the alleged invention to prevent release requires that the compositions be formulated in line with Mylan's construction." The Court finds Mylan's arguments unavailing.

The Court of Appeals for the Federal Circuit has explained that

> claim terms take on their ordinary and accustomed meanings unless the patentee demonstrated an intent to deviate from the ordinary and accustomed meaning of a claim term by redefining the term or by characterizing the invention in the intrinsic record using words or expressions of manifest exclusion or restriction, representing a clear disavowal of claim scope.

Superguide Corp. v. DirecTV Enterprises, Inc., 358 F.3d 870, 875 (Fed. Cir. 2004) (citation and

quotation marks omitted). While it is encouraged to look to intrinsic evidence such as the specification to see whether the patentee has redefined a claim term, it is important to remember the intended purposes of the specification and claim terms – specifications are intended to teach and claims are intended to claim. *See id.* (citing *SRI Int'l v. Matsushita Elec. Corp. of Am.*, 775 F. 2d 1107, 1121 n. 14 (Fed Cir. 1985) (en banc)). The specification "is not a substitute for, nor can it be used to rewrite, the chosen claim language" and "it is important not to import into a claim limitations that are not a part of the claim." *Id.* "For example, a particular embodiment appearing in the written description may not be read into a claim when the claim language is broader than the embodiment." *Id.* (citing *Electro Med. Sys. S.A. v. Cooper Life Sci., Inc.*, 34 F.3d 1048, 1054 (Fed. Cir. 1994)).

Looking at the claim terms, the Court notes that the language "remains intact" does not appear in the claim. In addition, the claim language here – "adapted to prevent release of the mycophenolate salt in the stomach and to release the mycophenolic salt in the upper part of the intestinal tract" – is broader than the adaptation in the specification – "coating which remains intact for at least 2 hours." Further, the Court does not believe that the specification evidences a clear disavowal of the broad scope of the claim. *See Liebel-Flarsheim Co. v. Medrad, Inc.*, 358 F.3d 898, 906 (Fed. Cir. 2004) ("Even when the specification describes only a single embodiment, the claims of the patent will not be read restrictively unless the patentee has demonstrated a clear intention to limit the claim scope using 'words or expressions of manifest exclusion or restriction.'" (quoting *Teleflex, Inc. v. Ficosa N. Am. Corp.*, 299 F.3d 1313, 1327 (Fed. Cir. 2002)). Accordingly, the Court declines to read "remains intact" into the construction of Term 3.

2. Term 4: "adapted to prevent release of mycophenolate in the stomach"

Term 4 appears in claims 1 and 11 of the '900 Patent. Novartis puts forth the following construction: "adapted with a pharmaceutically acceptable coating to prevent release of the

mycophenolate salt in the stomach." Mylan supports the construction: "formulating the composition with any pharmaceutically acceptable coating that remains intact in the stomach to prevent release of any kind of mycophenolate in the stomach."

Our analysis for the proper construction of this term will begin and end with the claim language itself. Claim 1 states: "A pharmaceutical composition comprising a mycophenolate salt, the composition being adapted to prevent release of mycophenolate in the stomach." Claim 11 states: "A pharmaceutical composition comprising a mycophenolate mono-sodium salt, the composition being adapted to prevent release [of] mycophenolate in the stomach . . ." A POSA reading those claims would obviously construe "mycophenolate" as "mycophenolate salt" because the patentee clearly used "mycophenolate" as a short form for "mycophenolate salt." It would be illogical to conclude otherwise as the invention is intending to prevent the release of the pharmaceutical composition, which the claims expressly state is comprised of mycophenolate salt. Quite simply, Mylan's construction is too broad; Novartis's construction governs.

D. Term 6 – "formulated to disintegrate selectively in the intestinal tract to release mycophenolate there"

This claim term appears in claim 1 of the '107 Patent. Novartis construes this term as follows: "formulated with a pharmaceutically acceptable coating to allow disintegration of the pharmaceutical composition and release of the mycophenolate salt in the intestinal tract, and to prevent disintegration of the pharmaceutical composition and release of the mycophenolate salt in the stomach." Mylan proposes that the proper construction is: "formulated to separate into one or more individual parts of the composition in the intestinal tract to release any form of mycophenolic acid in the intestinal tract." The parties dispute the construction of "mycophenolate," the inclusion of "pharmaceutically acceptable coating" into the construction, and what the word "selectively" modifies in the claim.

First, the Court construes "mycophenolate" to mean "mycophenolate salt." Claim 1 of the '107 Patent reads: "A pharmaceutical composition comprising a mycophenolate salt, the composition being formulated to disintegrate selectively in the intestinal tract to release mycophenolate there." The Court reaches this conclusion based on the same analysis for the meaning of "mycophenolate" presented in Term 4. Although the claim language in claim 1 of the '107 Patent differs from that of claims 1 and 11 of the '900 Patent, a POSA reading "mycophenolate" in claim 1 of the '107 Patent would similarly understand it to mean "mycophenolate salt."

Second, the Court will decline to include "pharmaceutically acceptable coating" in its construction. Although the specification provides for an embodiment of a composition with an enteric coating, the broad language of the claim does not require that the composition be formulated only with a pharmaceutically acceptable coating. Accordingly, it would be improper to read that particular embodiment into the claim. *See Superguide Corp.*, 358 F.3d at 875.

The final dispute between the parties concerning the construction of Term 6 appears to focus on the use of the word "selectively" in the claim term. Mylan argues that a POSA would understand that "disintegrate selectively" refers to "the loss or separation of selected parts of a substance." However, Novartis maintains that a POSA looking at the claim language in the context of the claim and specification would understand "disintegrate selectively" to mean allowing disintegration to occur in the place that is most suitable for that purpose (i.e., the upper part of the intestinal tract) and prevent disintegration in any other place (i.e., the stomach).

Looking to the claim language, the Court finds that the word "selectively" serves to modify "in the intestinal tract." A POSA looking to the specification would also glean that "selectively" referred to the place of disintegration rather than to "the loss or separation of selected parts of a substance." The specification expressly states: "The present invention provides in one aspect a pharmaceutical composition comprising a mycophenolate salt, the composition being adapted to

release mycophenolate in the upper part of the intestinal tract (hereinafter referred to as a composition of the invention)." ('107 Patent, col. 1, ll. 51-59 (emphasis added)). Therefore, a POSA reading "disintegrate selectively in the intestinal tract" in the claim term would understand that disintegration would occur in the intestinal tract. However, the language of the claim term is not so express as to require notation in the construction that disintegration and release of the mycophenolate salt would be prevented in the stomach. Thus, the proper construction of Term 6 is: "formulated to allow disintegration of the pharmaceutical composition and release of mycophenolate salt in the intestinal tract."

III. CONCLUSION

The Court has reviewed the parties' submissions and has held oral argument on the disputed terms; and

IT IS on this 10th day of August 2011 **ORDERED** that the following disputed terms shall be constructed as follows:

1. Term 1 – "pharmaceutically acceptable mycophenolate salt" – is construed to mean "any pharmaceutically acceptable cationic salt (preferably monosodium) of mycophenolic acid"; and

2. Terms 2 – "enteric coated" and "enteric coating" – are construed to mean "any pharmaceutically acceptable coating preventing the release of the active agent in the stomach and sufficiently disintegrating in the intestine tract (by contact with approximately neutral or alkaline intestine juices) to allow the resorption of the active agent through the walls of the intestinal tract" and "resorption" means "absorption"; and

3. Term 3 – "adapted to prevent release of the mycophenolate salt in the stomach and to release the mycophenolic salt in the upper part of the intestinal tract" – is

construed to mean "adapted with a pharmaceutically acceptable coating to prevent release of mycophenolate salt in the stomach and to release the mycophenolate salt in the duodenum, jejeunum and/or ileum"; and

4. Term 4 – "adapted to prevent release of mycophenolate in the stomach" – is construed to mean "adapted with a pharmaceutically acceptable coating to prevent release of the mycophenolate salt in the stomach"; and

5. Term 5 – "adapted to prevent release" was not construed by the Court as construction of both Terms 3 and 5 would be duplicative; and

6. Term 6 – "formulated to disintegrate selectively in the intestinal tract to release mycophenolate there" – is construed to mean "formulated to allow disintegration of the pharmaceutical composition and release of mycophenolate salt in the intestinal tract."

PETER G. SHERIDAN, U.S.D.J.

August 10, 2011